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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,579	04/13/2005	Jorg Sturzebecher	50125/097001	1588
21559	7590	07/17/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
			1621	
			NOTIFICATION DATE	DELIVERY MODE
			07/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/506,579	Applicant(s) STURZEBECKER ET AL.	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 28, 29 and 34-38 are is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 19 March 2008 is acknowledged. The election of the compound of Example 8 in the specification is acknowledged. Claims 21, 28, 29 34-38 and 40 are readable thereon. The traversal is on the ground(s) that there is unity of invention between the product of claim 21 and the method of claim 29. This is not found persuasive because the genus claimed in claim 21 cannot form the basis for unity of invention since the prior art (*vide infra*) discloses compounds of the invention. The genus therefore lacks the special technical feature required to establish unity. The requirement is still deemed proper and is therefore made FINAL. Claims 21, 28, 29 34-38 and 40 are examined below. Claims 22-27, 30-33 and 39 are held withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 21, 28, 29 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites (Line 31) the limitation " R_5 is $-(CH_2)_g(CH_3)_h...$ in which $g + h = 0, 1, 2$ or 2 ". When R_5 is $-(CH_2)_g(CH_3)_h$ and $g+h = 0$, an incomplete structure is defined. Claim 21 and its dependents is therefore rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21 and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stürzebecher et al (DE 10029014-A1 12-2001). Stürzebecher discloses (Paragraph 0025) the compound benzensulfonyl-D SerGly\$-amidinobenzylamide, as the hydrochloride salt. This corresponds to a compound of the invention in which R_4 is C_1 alkyl. Stürzebecher discloses (Paragraphs [0020] and [0025]) the sequential coupling of the amino acids to 4-actyloxamidinobenzylamine. Stürzebecher discloses (Paragraph [0026]) buffered pharmaceutical solutions of the compound.
5. Claim 21, 34, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura et al (Bioorganic and Medicinal Chemistry Letters, 2000, 10, pages 983-987). Tamura discloses (Page 985, Scheme 3) the trifluoroacetate salt of

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the compound 1a in which U is a heterocyclohexyl radical, R₅ is COOR₁₂, R₁₂ = branched C₄ alkyl. and n=0 in V. Tamura discloses (Page 985, Table I) pharmaceutical solutions of these compounds as well.

Claim Objections

6. Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

7. Claims 28, 29 and 40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
8. Claims 28, 29 and 40 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The elected specie is free of art. The closest prior art. Stürzebecher et al (DE 10029014-A1 12-2001) and Tamura et al (Bioorganic and Medicinal Chemistry Letters, 2000, 10, pages 983-987) either alone or together neither disclose nor fairly suggest the instantly claimed compounds in which P₂= Lys or Arg residues.

Conclusion

9. Claims 21-40 are pending. Claims 21, 28, 29 and 34-38 are rejected. Claim 40 is objected to. Claims 22-27, 30-33 and 39 are held withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner, Art Unit 1621